Amendments to the Claims

Please cancel claims 20 and 22.

Please amend claims 2, 16 and 18 as presented below.

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Canceled)

2. (Currently Amended) An in vitro method for diagnosing a subject as having or as being at risk for having a thrombotic disorder associated with activated protein C (APC)-resistant factor V or Va, wherein the subject is presently on an oral anticoagulant regimen, the method comprising:

a) contacting a test sample comprising a coagulation factor V or Va-containing specimen from the subject with a procoagulant reagent, factor V-deficient plasma to provide coagulation factors other than factors V or Va, calcium present in a concentration from about 5 mM to 15 mM, and APC present at from about 100 ng/ml to 10 ug/ml in a test reaction, wherein the test sample is initially diluted from about 1/40 to 1/80; and

b) comparing the clotting time for the test reaction to the clotting time for a control reaction carried out under the same conditions as the test reaction, but with a control sample comprising a coagulation factor V or Va-containing specimen from an individual not having or not at risk of having a thrombotic disorder associated with APC-resistant factor V or Va, wherein:

i) detection of a decreased clotting time in the test reaction relative to the control reaction indicates a diagnosis of a thrombotic disorder associated with APC-resistant factor V or Va; and

ii) detection of a similar clotting time in the test reaction relative to the control reaction indicates that the subject does not have or is not at risk of developing a thrombotic disorder associated with APC-resistant factor V or Va.

3. (Previously Presented) The method of claim 2, wherein the specimen from the subject is previously frozen plasma.

4. (Previously Presented) The method of claim 2, wherein the thrombotic disorder is thrombophilia.

5. (Previously Presented) The method of claim 2, wherein the thrombotic disorder is due to a factor V mutation.

6. (Previously Presented) The method of claim 5, wherein the mutation results in a change from arginine to glutamine at position 506 of factor V.

7. (Previously Presented) The method of claim 2, wherein the procoagulant reagent comprises tissue factor.

8. (Previously Presented) The method of claim 2, wherein the procoagulant reagent comprises a phospholipid.

9. (Previously Presented) The method of claim 8, wherein the phospholipid is present at a concentration of about 5-100 uM in the test reaction.

10. (Previously Presented) The method of claim 8, wherein the phospholipid is present at a concentration of about 10-50 uM in the test reaction.

11. (Previously Presented) The method of claim 2, wherein the procoagulant reagent comprises an activator of the intrinsic coagulation pathway.

12. (Previously Presented) The method of claim 11, wherein the activator is a clotting factor selected from the group consisting of factor Xa, factor IXa, factor XIa and factor XIIa.

13. (Previously Presented) The method of claim 2, wherein the procoagulant is a reagent selected from the group consisting of kallikrein, Russell's viper venom, micronized silica particles, ellagic acid, sulfatides, kaolin, and tissue thromboplastin.

14. (Previously Presented) The method of claim 2 wherein the specimen from the subject is diluted in a physiologically balanced buffer.

15. (Previously Presented) The method of claim 2, wherein the APC in the test reaction is present at from about 200 ng/ml to 1 ug/ml.

16. (Currently Amended) The method of claim 2, wherein the anticoagulant is ~~heparin~~ warfarin.

17. (Previously Presented) The method of claim 2, further comprising setting up a no-APC test reaction, carried out under the same conditions as the test reaction except that no APC is added to the reaction, wherein a clotting time for the test reaction that is similar to, or faster than, a clotting time for the no-APC reaction is indicative of a subject having a thrombotic disorder associated with a homozygous mutation from arginine to glutamine at position 506 of factor V.

18. (Currently Amended) An in vitro method for diagnosing a subject as having or as being at risk for having a thrombotic disorder associated with activated protein C (APC)-resistant factor V or Va, wherein the subject is presently on an oral anticoagulant regimen, the method comprising:

a) contacting a test sample comprising a coagulation factor V or Va-containing specimen from the subject with a procoagulant reagent, factor V-deficient plasma to provide coagulation factors other than factors V or Va, calcium sufficient to initiate clotting, and APC, wherein the test sample is initially diluted from about 1/40 to 1/80; and

b) comparing the clotting time for the test reaction to the clotting time for a no-APC control reaction carried out under the same conditions as the test reaction, but without adding APC,

wherein detection of a similar clotting time or faster clotting time in the test reaction relative to the no-APC control reaction indicates a diagnosis of a thrombotic disorder associated with APC-resistant factor V or Va.

19. (Previously Presented) The method of claim 18, wherein a clotting time for the test reaction that is faster than, a clotting time for the no-APC reaction is indicative of a subject having a thrombotic disorder associated with a homozygous mutation in factor V or Va rendering the factor APC-resistant.

20. (Canceled)

21. (Currently Amended) The method of claim ~~20~~ 18 ,wherein the mutation is a change from arginine to glutamine at position 506 of factor V.

22. (Canceled)